

Application No.: 10/726,585

Docket No.: N9810.0034/P034

**AMENDMENTS TO THE CLAIMS**

1.-32. (Cancelled).

33. (Currently amended). The method composition of claim 124[[32]], wherein the spray composition further comprises ~~comprising~~ a flavoring agent in an amount between 0.05 and 10 percent by weight of the total composition.

34. (Currently amended). The method composition of claim 33, wherein the polar solvent is present in an amount between 20 and 97 percent by weight of the total composition, the active compound is present in an amount between 0.1 and 15 percent by weight of the total composition, the propellant is present in an amount between 2 and 5 percent by weight of the composition, and the flavoring agent is present in an amount between 0.1 and 5 percent by weight of the total composition.

35. (Currently amended). The method composition of claim 34, wherein the polar solvent is present in an amount between 25 and 97 percent by weight of the total composition, the active compound is present in an amount between 0.2 and 25 percent by weight of the total composition, the propellant is present in an amount between 2 and 4 percent by weight of the composition, and flavoring agent is present in an amount between 0.1 and 2.5 percent by weight of the total composition.

36. (Currently amended). The method composition of claim 124[[32]], wherein the polar solvent is selected from the group consisting of polyethyleneglycols having a molecular weight between 400 and 1000, C<sub>2</sub> to C<sub>8</sub> mono- and poly-alcohols, and C<sub>7</sub> to C<sub>18</sub> alcohols of linear or branched configuration.

37. (Currently amended). The method composition of claim 36, wherein the polar solvent comprises aqueous polyethylene glycol.

38. (Currently amended). The method composition of claim 36, wherein the polar solvent comprises aqueous ethanol.

Application No.: 10/726,585

Docket No.: N9810.0034/P034

39. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is an acetylcholinesterase inhibitor selected from the group consisting of galantamine, neostigmine, physostigmine, and edrophonium, and mixtures thereof.

40. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is a nerve impulse inhibitor selected from the group consisting of levobupivacaine, lidocaine, prilocaine, mepivacaine, propofol, rapacuronium bromide, ropivacaine, tubocurarine, atracurium, doxaurium, mivacurium, pancuronium, vecuronium, pipecuronium, rocuronium, and mixtures thereof.

41. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is an anti-cholinergic selected from the group consisting of amantadine, ipratropium, oxitropium, dicycloverine, and mixtures thereof.

42. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is an anti-convulsant selected from the group consisting of acetazolamide, carbamazepine, clonazepam, diazepam, divalproex, ethosuximide, lamotrigine acid, levetiracetam, oxcarbazepine, phenobarbital, phenytoin, pregabalin, primidone, remacemide, trimethadione, topiramate, vigabatrin, zonisamide, and mixtures thereof.

43. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is an anti-psychotic selected from the group consisting of amisulpride, aripiprazole, bifemelane, bromperidol, clozapine, chlorpromazine, haloperidol, iloperidone, loperidone, olanzapine, quetiapine, fluphenazine, fumarate, risperidone, thiothixene, thioridazine, sulpride, ziprasidone, and mixtures thereof.

44. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is an anxiolytic agent selected from the group consisting of amitriptyline, atracurium, buspirone, chlorzoxazone, clorazepate, cisatracurium,

Application No.: 10/726,585

Docket No.: N9810.0034/P034

cyclobenzaprine, eperisone, esopiclone, hydroxyzine, mirtazapine, mivacurium, pagoclone, sulperide, zaleplon, zopiclone, and mixtures thereof.

45. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is a dopamine metabolism inhibitor selected from the group consisting of entacapone, lasebamide, selegiline, tolcapone, and mixtures thereof.

46. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is an agent to treat post stroke sequelae selected from the group consisting of glatiramer, interferon beta 1 A, interferon beta 1B, estradiol, progesterone, and mixtures thereof.

47. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is a neuroprotectant selected from the group consisting of donepezil, memantine, nimodipine, riluzole, rivastigmine, tacrine, TAK147, xaliproden, and mixtures thereof.

48. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is an agent to treat Alzheimer's disease selected from the group consisting of carbidopa, levodopa, tacrine, donepezil, rivastigmine, galantamine, and mixtures thereof.

49. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is a neurotransmitter selected from the group consisting of acetylcholine, serotonin, 5-hydroxytryptamine (5-HT), GABA, glutamate, aspartate, glycine, histamine, epinephrine, norepinephrine, dopamine, adenosine, ATP, nitric oxide, and mixtures thereof.

50. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is a neurotransmitter agonist selected from the group consisting of almotriptan, aniracetam, atomoxetine, bencscrazide, bromocriptine,

Application No.: 10/726,585

Docket No.: N9810.0034/P034

bupropion, cabergoline, citalopram, clomipramine, desipramine, diazepam, dihydroergotamine, doxepin duloxetine, eletriptan, escitalopram, fluvoxamine, gabapentin, imipramine, moclobemide, naratriptan, nefazodone, nefiracetam, acamprosate, nicergoline, nortryptiline, paroxetine, pergolide, pramipexole, rizatriptan, ropinirole, sertraline, sibutramine, sumatriptan, tiagabine, trazodone, venlafaxine, zolmitriptan, and mixtures thereof.

51. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is a sedative selected from the group consisting of dexmedetomidine, eszopiclone, indiplon, zolpidem, zalcplon, and mixtures thereof.

52. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is an agent for treating attention deficit disorder selected from the group consisting of amphetamine, dextroamphetamine, methylphenidate, pemoline, and mixtures thereof.

53. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is an agent for treating narcolepsy selected from the group consisting of modafinil, mazindol, and mixtures thereof.

54. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is an anti-depression agent selected from the group consisting of amitriptyline, amoxapine, bupropion, clomipramine, clomipramine, clorgyline, desipramine, doxepin, fluoxetine, imipramine, isocarboxazid, maprotiline, mirtazapine, nefazodone, nortriptyline, paroxetine, phenelzine, protriptyline, sertraline, tranylcypromine, trazodone, venlafaxine, and mixtures thereof.

55. (Currently amended). The ~~method composition~~ of claim 124[[32]], wherein the active compound is an agent for treating Parkinson's disease selected from the group consisting of amantadine, bromocriptine, carvidopa, levodopa, pergolide, selegiline, and mixtures thereof.

Application No.: 10/726,585

Docket No.: N9810.0034/P034

56. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is the benzodiazepine antagonist flumazenil.

57. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is the neurotransmitter antagonist deramciclane.

58. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is a stimulant selected from the group consisting of amphetamine, dextroamphetamine, dinoprostone, methylphenidate, modafinil, pemoline, and mixtures thereof.

59. (Currently amended). The method composition of claim 124[[32]], wherein the active compound is the tranquilizer mesoridazine.

60. (Currently amended). The method composition of claim 33, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

61. (Currently amended). The method composition of claim 124[[32]], wherein the propellant is selected from the group consisting of propane, *N*-butane, *iso*-butane, *N*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

Claims 62.-92. (Cancelled).

93. (Currently amended). The method composition of claim 125[[92]], wherein the spray composition further comprises comprising a flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

94. (Currently amended). The method composition of claim 93, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

Application No.: 10/726,585

Docket No.: N9810.0034/P034

Claim 95. (Canceled).

96. (Currently amended). The ~~method composition~~ of claim 126[[95]], wherein the propellant is present in an amount between 20 and 70 percent by weight of the total composition, the non-polar solvent is present in an amount between 25 and 75 percent by weight of the total composition, the active compound is present in an amount from between 0.25 and 35 percent by weight of the total composition, and the flavoring agent is present in an amount between 2 and 7.5 percent by weight of the total composition.

97. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the propellant is selected from the group consisting of propane, *n*-butane, *iso*-butane, *n*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

98. (Currently amended). The ~~method composition~~ of claim 97, wherein the propellant is *n*-butane or *iso*-butane and has a water content of not more than 0.2 percent and a concentration of oxidizing agents, reducing agents, Lewis acids, and Lewis bases of less than 0.1 percent.

99. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the solvent is selected from the group consisting of (C<sub>2</sub>-C<sub>24</sub>) fatty acid (C<sub>2</sub>-C<sub>6</sub>) esters, C<sub>7</sub>-C<sub>18</sub> hydrocarbons of linear or branched configuration, C<sub>2</sub>-C<sub>6</sub> alkanoyl esters, and triglycerides of C<sub>2</sub>-C<sub>6</sub> carboxylic acids.

100. (Currently amended). The ~~method composition~~ of claim 99, wherein the solvent is miglyol.

101. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is an acetylcholinesterase inhibitor[[s]] selected from the group consisting of galantamine, neostigmine, physostigmine, and edrophonium, and mixtures thereof.

Application No.: 10/726,585

Docket No.: N9810.0034/P034

102. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is a nerve impulse inhibitor selected from the group consisting of levobupivacaine, lidocaine, prilocaine, mepivacaine, propofol, rapacuronium bromide, ropivacaine, tubocurarine, atracurium, doxaurium, mivacurium, pancuronium, vecuronium, pipecuronium, rocuronium, and mixtures thereof.

103. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is an anti-cholinergic selected from the group consisting of amantadine, ipratropium, oxitropium, dicycloverine, and mixtures thereof.

104. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is an anti- convulsant selected from the group consisting of acetazolamide, carbamazepine, clonazepam, diazepam, divalproex, ethosuximide, lamotrigine acid, levetriacetam, oxcarbazepine, phenobarbital, phenytoin, pregabalin, primidone, remacemide, trimethadione, topiramate, vigabatrin, zonisamide, and mixtures thereof.

105. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is an anti-psychotic selected from the group consisting of amisulpride, aripiprazole bifemelane, bromperidol, clozapine, chlorpromazine, haloperidol, iloperidone loperidone, olanzapine, quetiapine, fluphenazine, fumarate, risperidone, thiothixene, thioridazine, sulpride, ziprasidone, and mixtures thereof.

106. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is an anxiolytic agent selected from the group consisting of amitryptiline, atracurium, buspirone, chlorzoxazone, clorazepate, cisatracurium, cyclobenzaprine, cperisone, esopiclone, hydroxyzine, mirtazapine, mivacurium, pagoclone, sulperide, zalcplon, zopiclone, and mixtures thereof.

Application No.: 10/726,585

Docket No.: N9810.0034/P034

107. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is a dopamine metabolism inhibitor selected from the group consisting of entacapone, lazebemide, selegiline, tolcapone, and mixtures thereof.

108. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is an agent to treat post stroke sequelae selected from the group consisting of glatiramer, interferon beta 1A, interferon beta 1B, estradiol, progesterone, and mixtures thereof.

109. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is a neuroprotectant selected from the group consisting of donepezil, memantine, nimodipine, riluzole, rivastigmine, tacrine, TAK147, xaliproden, and mixtures thereof.

110. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is an agent to treat Alzheimer's disease selected from the group consisting of carbidopa, levodopa, tacrine, donepezil, rivastigmine, galantamine, and mixtures thereof.

111. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is a neurotransmitter selected from the group consisting of acetylcholine, serotonin, 5-hydroxytryptamine (5-HT), GABA, glutamate, aspartate, glycine, histamine, epinephrine, norepinephrine, dopamine, adenosine, ATP, nitric oxide, and mixtures thereof.

112. (Currently amended). The ~~method composition~~ of claim 125[[92]], wherein the active compound is a neurotransmitter agonist selected from the group consisting of almotriptan, aniracetam, atomoxetine, benserazide, bromocriptine, bupropion, cabergoline, citalopram, clomipramine, desipramine, diazepam, dihydroergotamine, doxepin, duloxetine, eletriptan, escitalopram, fluvoxamine, gabapentin, imipramine, moclobemide, naratriptan, nefazodone, nefiracetam, acamprosate,



Application No.: 10/726,585

Docket No.: N9810.0034/P034

nicergoline, nortryptiline, paroxetine, pergolide, pramipexole, rizatriptan, ropinirole, sertraline, sibutramine, sumatriptan, tiagabine, trazodone, venlafaxine, zolmitriptan, and mixtures thereof.

113. (Currently amended). The method composition of claim 125[[92]], wherein the active compound is a sedative selected from the group consisting of dexmedetomidine, eszopiclone, indiplon, zolpidem, zaleplon, and mixtures thereof.

114. (Currently amended). The method composition of claim 125[[92]], wherein the active compound is an agent for treating attention deficit disorder selected from the group consisting of amphetamine, dextroamphetamine, methylphenidate, pemoline, and mixtures thereof.

115. (Currently amended). The method composition of claim 125[[92]], wherein the active compound is an agent for treating narcolepsy selected from the group consisting of modafinil, mazindol, and mixtures thereof.

116. (Currently amended). The method composition of claim 125[[92]], wherein the active compound is an anti-depression agent selected from the group consisting of amitriptyline, amoxapine, bupropion, clomipramine, clomipramine, clorgyline, desipramine, doxepin, fluoxetine, imipramine, isocarboxazid, maprotiline, mirtazapine, nefazodone, nortriptyline, paroxetine, phenelzine, protriptyline, sertraline, tranylcypromine, trazodone, venlafaxine, and mixtures thereof.

117. (Currently amended). The method composition of claim 125[[92]], wherein the active compound is an agent for treating Parkinson's disease selected from the group consisting of amantadine, bromocriptine, carvidopa, levodopa, pergolide, selegiline, and mixtures thereof.

118. (Currently amended). The method composition of claim 125[[92]], wherein the active compound is the benzodiazepine antagonist flumazenil.

Application No.: 10/726,585

Docket No.: N9810.0034/P034

119. (Currently amended). The method composition of claim 125[[92]], wherein the active compound is the neurotransmitter antagonist deramciclanc.

120. (Currently amended). The method composition of claim 125[[92]], wherein the active compound is a stimulant selected from the group consisting of amphetamine, dextroamphetamine, dinoprostone, methylphenidate, methylphenidate, modafinil, pemoline, and mixtures thereof.

121. (Currently amended). The method composition of claim 125[[92]], wherein the active compound is the tranquilizer mesoridazine.

Claims 122 - 123 (Canceled).

124. (New) A method for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of the active compound through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

spraying the oral mucosa of the mammal with a buccal spray composition, containing a pharmacologically active compound dissolved in a pharmacologically acceptable solvent, comprising in weight percent of the composition:

an active compound in an amount of between 0.1 and 25 percent selected from the group consisting of acetylcholinesterase inhibitors, nerve impulse inhibitors, anticholinergics, anti-convulsants, anti-psychotics, anxiolytic agents, dopamine metabolism inhibitors, agents to treat post stroke sequelae, neuroprotectants, agents to treat Alzheimer's disease, neurotransmitters, neurotransmitter agonists, sedatives, agents for treating attention deficit disorder, agents for treating narcolepsy, central adrenergic antagonists, anti-depression agents, agents for treating Parkinson's disease, benzodiazepine antagonists, stimulants, neurotransmitter antagonists, tranquilizers, and mixtures thereof;

a polar solvent in an amount between 10 and 97 percent; and

Application No.: 10/726,585

Docket No.: N9810.0034/P034

a propellant in an amount between 2 and 10 percent, wherein said propellant is a C<sub>3</sub> to C<sub>8</sub> hydrocarbon of linear or branched configuration.

125. (New) A method for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of the active compound through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

spraying the oral mucosa of the mammal with a buccal spray composition, containing a pharmacologically active compound dissolved in a pharmacologically acceptable solvent, comprising in weight percent of the composition:

an active compound in an amount between 0.05 and 50 percent selected from the group consisting of acetylcholinesterase inhibitors, nerve impulse inhibitors, anti-cholinergics, anti-convulsants, anti-psychotics, anxiolytic agents, dopamine metabolism inhibitors, agents to treat post stroke sequelae, neuroprotectants, agents to treat Alzheimer's disease, neurotransmitters, neurotransmitter agonists, sedatives, agents for treating attention deficit disorder, agents for treating narcolepsy, central adrenergic antagonists, anti-depression agents, agents for treating Parkinson's disease, benzodiazepine antagonists, stimulants, neurotransmitter antagonists, tranquilizers, and mixtures thereof;

a non-polar solvent in an amount between 19 and 85 percent; and

a propellant in an amount between 5 and 80 percent, wherein said propellant is a C<sub>3</sub> to C<sub>8</sub> hydrocarbon of linear or branched configuration.

126. (New) A method for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of the active compound through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

Application No.: 10/726,585

Docket No.: N9810.0034/P034

spraying the oral mucosa of the mammal with a buccal spray composition, containing a pharmacologically active compound dissolved in a pharmacologically acceptable solvent, comprising in weight percent of the composition:

an active compound in an amount between 0.01 and 40 percent selected from the group consisting of acetylcholinesterase inhibitors, nerve impulse inhibitors, anti-cholinergics, anti-convulsants, anti-psychotics, anxiolytic agents, dopamine metabolism inhibitors, agents to treat post stroke sequelae, neuroprotectants, agents to treat Alzheimer's disease, neurotransmitters, neurotransmitter agonists, sedatives, agents for treating attention deficit disorder, agents for treating narcolepsy, central adrenergic antagonists, anti-depression agents, agents for treating Parkinson's disease, benzodiazepine antagonists, stimulants, neurotransmitter antagonists, tranquilizers, and mixtures thereof;

a non-polar solvent in an amount between 25 and 89 percent;

a propellant in an amount between 10 and 70 percent, wherein said propellant is a C<sub>2</sub> to C<sub>8</sub> hydrocarbon of linear or branched configuration; and

a flavoring agent in an amount between 1 and 8 percent.